CLAIMS

1. A method of enhancing an immune response to an antigen in a mammal, comprising administering to the mammal a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof, and 2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a saponin adjuvant.

2. A method according to claim 2 wherein the antigen or immunogenic derivative thereof is derived from an organism selected from the following group: Human Immunodeficiency virus HIV-1, human herpes simplex viruses, cytomegalovirus, Rotavirus, Epstein Barr virus, Varicella Zoster Virus, from a hepatitis virus such as hepatitis B virus, hepatitis A virus, hepatitis C virus and hepatitis E virus, from Respiratory Syncytial virus, parainfluenza virus, measles virus, mumps virus, human papilloma viruses, flaviviruses or Influenza virus, from *Neisseria spp, Moraxella spp, Bordetella spp; Mycobacterium spp.*, including *M. tuberculosis; Escherichia spp*, including *enterotoxic E. coli; Salmonella spp,; Listeria spp; Helicobacter spp; Staphylococcus spp.*, including *S. aureus, S. epidermidis;; Borrelia spp; Chlamydia spp.*, including *C. trachomatis, C. pneumoniae; Plasmodium spp.*, including *P. falciparum; Toxoplasma spp., Candida spp.*

3. A method of reducing the severity of a cancer in a patient, comprising administering to a patient in need thereof a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof and 2) an immunogenic composition comprising a tumour associated antigen or immunogenic derivative thereof and a saponin adjuvant.

4. A method according to claim 3, wherein the tumour associated antigen or immunogenic derivative thereof is selected from the group comprising: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, or her 2 neu.

5. A method according to any of claims 1 to 4, wherein the IL-18 polypeptide or bioactive fragment or variant thereof and the immunogenic composition are administered simultaneously, separately or sequentially in any order.

6. A method according to claim 5 wherein the the TH-1 cytokine and the immunogenic composition are administered simultaneously in the form of a combined pharmaceutical preparation.

7. A method according to any of claims 1 to 6, wherein the IL-18 polypeptide or bioactive fragment or variant thereof is from human or murine origin.

8. A method according to claim 7, wherein IL-18 is the polypeptide of SEQ ID NO.6 or SEQ ID NO.7 or bioactive fragment or derivative thereof.

9. A method according to any of claims 1 to 8, wherein the saponin adjuvant is QS-21 or QS-17.

10. A combined preparation comprising as active ingredients the following individual components: (1) IL-18 polypeptide or bioactive fragment or variant thereof and (2) immunogenic composition comprising an antigen and a saponin adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, autoimmune diseases and related conditions.

11. A combined preparation according to claim 10 wherein components (1) and (2) are admixed in a composition.

12. A combined preparation according to claim 10 or 11 wherein the immunogenic composition comprises a tumour associated antigen or immunogenic derivative thereof and is prophylactically or therapeutically active against cancer.

13. A combined preparation according to claim 12 wherein the tumour associated antigen or immunogenic derivative thereof is selected from the group comprising: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-

BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, or her 2 neu.

14. A combined preparation according to any of claims 10 to 13, wherein the IL-18 polypeptide or bioactive fragment or variant thereof is from human or murine origin.

15. A combined preparation according to claim 14, wherein IL-18 is the polypeptide of SEQ ID NO.6 or SEQ ID NO.7 or bioactive fragment or derivative thereof.

16. A combined preparation according to any of claims 10 to 15, wherein the saponin adjuvant is QS-21 or QS-17.

17. Combined preparation as claimed in any of claims 10 to 16 in which the immunogenic composition additionally comprises an immunostimulant chemical selected from the group comprising: 3D-MPL, cholesterol, CpG oligonucleotide containing at least one immunostimulatory CG dinucleotide, aluminium hydroxide, aluminium phosphate, tocopherol, and an oil in water emulsion or a combination of two or more of the said adjuvants.

18. Combined preparation as claimed in claim 17 wherein the immunogenic composition adjuvant comprises 3D-MPL, QS21, cholesterol, an oil in water emulsion.

19. Combined preparation as claimed in claim 18 wherein the oil in water emulsion comprises squalene, tocopherol and polyoxyethylenesorbitan monooleate (Tween 80).

20. Combined preparation as claimed in claim 17 wherein the immunogenic composition comprises QS21, cholesterol and a CpG oligonucleotide containing at least one immunostimulatory CG dinucleotide.

21. Combined preparation as claimed in any of claims 10 to 20, wherein both active components are in the form of injectable solutions.

22. A pharmaceutical kit comprising as active ingredients the following individual components: (1) an IL-18 polypeptide or bioactive fragment thereof and (2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, and auto-immune diseases.

23. A pharmaceutical kit according to claim 22 wherein the immunogenic composition comprises a tumour associated antigen or immunogenic derivative thereof and is prophylactically or therapeutically active against cancer.

24. A pharmaceutical kit according to claim 23 wherein the tumour associated antigen or immunogenic derivative thereof is selected from the group comprising: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, or her 2 neu.

25. A combined preparation as claimed in any of claims 10 to 20 for use in medecine.

26. A method as claimed in any of claims 1 to 9 which comprises the use of a combined preparation according to any of claims 10 to 20.

27. Use of an IL-18 polypeptide or bioactive fragment or variant thereof in the manufacture of a medicament for the prophylaxis and/or treatment of patients suffering from or susceptible to infectious diseases, cancer, autoimmune diseases and related conditions, and already primed with an immunogenic composition comprising an antigen or immunogenic derivative thereof and a saponin adjuvant.

28. Use of an immunogenic composition comprising an antigen or immunogenic derivative thereof and a saponin adjuvant in the manufacture of a medicament for the treatment of patients suffering from or susceptible to infectious diseases, cancer, autoimmune diseases and related conditions, and already primed with an IL-18 polypeptide or immunogenic fragment or variant thereof.

29. Use according to claim 27 or 28 wherein the antigen is a tumour associated antigen and the cancer is selected from the group comprising: breast cancer, lung cancer, NSCLC, colon cancer, melanoma, ovarian cancer, bladder cancer, head and neck squanmous carcinoma, oesophagus cancer.

30. Use according to any of claims 27 to 29, wherein the IL-18 polypeptide or bioactive fragment or variant thereof is from human or murine origin.

31. Use according to claim 30, wherein IL-18 is the polypeptide of SEQ ID NO.6 or SEQ ID NO.7 or bioactive fragment or derivative thereof.

32. Use according to any of claims 27 to 31 wherein the saponin adjuvant is QS-21 or QS-17.